REMARKS/ARGUMENTS

This amendment is responsive to the Office Action dated April 20, 2004. Claims 1 – 28 and 30 – 41 are pending in the application. Those claims stand rejected. By way of this amendment, the Applicant has amended claims 1, 6 – 7, 13, 22 – 27, 30 – 32, and 35 – 39, and has canceled claims 5 and 10.

Objection under 35 U.S.C. §132 and Rejection under 35 U.S.C. §112, First Paragraph

The claims are objected to as containing new matter under 35 U.S.C. §132 and are rejected for failing to comply with the written description requirement under 35 U.S.C. §112, First Paragraph. The objection and rejection concern the recitation of a coprecipitant having a molecular weight of 1,000 Da that was moved from originally filed dependent claim 29 and incorporated into claims 1, 6, 22-27, and 30-32 by the most recent amendment. By current amendment, Applicant has removed the previously added 1,000 Da recitation from claims 1, 6, 22-27, and 30-32, thereby obviating the new matter objection and the written description rejection.

Rejections in view of the Randen Reference

Claims 6- 8, 10 – 12, 22, 24, 25, and 32 are rejected under 35 U.S.C. §102 and claims 1 – 12, 20 – 25, 27, and 32 – 41 are rejected under 35 U.S.C. §103 in view of the Randen reference.

According to the Office Action, Randen teaches coprecipitation of enzymes with a water-soluble starch by preparing an aqueous solution of enzymes and starch, and mixing the solution with organic solvent to cause precipitation.

The claims of the application recite a water soluble particle or method of making particles having a coprecipitant core, i.e. a dense crystalline core with dehydrated protein located at or close to the particle surface (page 12, l. 8 – 12). Here, Randen has not been shown to disclose, teach, or suggest a particle or manner of making a particle with a coprecipitant core. In contrast, Randen discloses that the enzyme is physically entrapped within the coprecipitant support matrix (p. 765, col. 2). So, if anything, Randen teaches away from the formation of a coprecipitant core.

The attached Declaration of Barry D. Moore and associated experimental data demonstrate that the starch-protein particles prepared in accordance with the Randen method are largely amorphous, which is shown from the SEM images and the Differential Scanning Calorimeter (DSC) studies. This is consistent with the statement in Randen that the enzyme is physically interspersed within the coprecipitate matrix (p. 765, col. 2). In contrast, the particles according to the claimed invention have a coprecipitant core, as clearly recited in each of the independent claims. Such a coprecipitant core would have sharp DSC melting points indicating high crystalinity such as the example prepared according to the claimed method, using glycine as a coprecipitant, shown in Figure 1D.

The claims have been amended to recite that the coprecipitant is selected from a particular list of compounds, not including starch. Randen fails to disclose, teach, or suggest a particle or manner of making a particle using anything other than starch as the coprecipitant. It is respectfully submitted that the recited coprecipitant core and specific coprecipitant compounds distinguish the claims from the Randen reference, and that one of skill in the art would not be motivated to use coprecipitants outside the teaching of Randen to form a particle having a fundamentally different physical configuration than the Randen particle.

Several of the product claims recite a size limitation of particles less than 50 μm. The Office Action states that particles of that size would be obtained by the milling operation disclosed in Randen. However, even if Randen were assumed to initially form particles having Applicants' coprecipitant core, the milling disclosed by Randen would destroy the coprecipitant core structure of any particles being milled, thereby further eliminating any chance of obtaining the claimed particles of less than 50 μm comprising a coprecipitant core with a dehydrated biological macromolecule coated thereon (Claim 1).

The Office has imposed an obligation upon the Applicant to explain the criticality of the coprecipitant core of the claimed invention versus the "biological macromolecule intermingled with the coprecipitant" of the prior art (pp. 7 - 8 of Office Action). Criticality is at issue when species of a claimed invention overlap prior art. Here, the experimental data submitted with the above-referenced Declaration, in conjunction with the discussion above, shows the distinctions

between the claimed particle and the Randen particle. Since the claims have been shown to be novel over the cited references, any issues of criticality have been obviated.

In summary, Randen does not disclose, teach, or suggest the recited particle or method of making the recited particle, explicitly or inherently.

Rejections in view of the Capone Reference

Claims 1 – 5, 24 – 28, 30, and 40 are rejected under 35 U.S.C. §102 and claims 1 – 12, 20 – 28, and 30 – 41 are rejected under 35 U.S.C. §103 in view of the Capone reference.

Capone relates to proteins adsorbed on the surface of zymosan particles or polymeric beads. However, Capone does not disclose the water soluble particles that are recited in each of the rejected claims.

A fundamental feature that makes the particles formed in Capone different from the particles according to the claimed invention, is that the particles in Capone are not water-soluble (see p. 2, lines 24 to 27; Ex. 1, lines 113-114; Ex. 2, lines 5-6). Since the recited particles are water-soluble and because the recited method produces water-soluble particles, the insoluble particles of Capone do not anticipate the claimed composition or method.

The claimed particle and method would not be obvious in view of the Capone reference because Applicants' use of a water-soluble coprecipitant to obtain the recited water-soluble particle is contrary to and inconsistent with the teachings of the Capone reference, which teaches use of an insoluble polymer (p.2, lines 74 and 127) to produce an insoluble particle. If anything, Capone teaches away from the claimed particle and method. Therefore, the claims are not obvious in view of Capone.

Rejections under 35 U.S.C. §103 in view of Novo '919

Claims 22 and 32 are rejected under 35 U.S.C. §103 in view of the Novo '919 reference. The Office Action states that Novo teaches a method of crystallizing protein from a protein solution. In contrast, claims 22 and 32 recite a method of isolating a protein or other biological material from an aqueous solution by use of a coprecipitant. In addition, claim 22 has been

amended to recite (claim 32 already recites) the resultant water soluble particle having a coprecipitant core. Novo fails to disclose the use of a coprecipitant to isolate protein from solution and fails to disclose the resultant formation of a particle having a coprecipitant core.

The rejected claims and the Novo method are further distinguished by the time required for precipitation/crystallization. Claims 22 and 32 recite that coprecipitation occurs immediately after mixing of the macromolecule/coprecipitant solution with an organic solvent. The Novo method is not immediate, with crystallization taking anywhere from 6 to 48 hours (page 17, lines 4 – 15).

There is no teaching or suggestion in Novo that a coprecipitant could be used to separate the protein from solution by forming particles having a macromolecule coated upon a coprecipitant core. The Office Action states that it would have been obvious to modify the Novo reference to obtain Applicants' claimed method since the same materials are used. However, the same materials are not used. Novo is silent as to the use of the recited coprecipitants. Without the teaching of a coprecipitant or coprecipitation, one of ordinary skill in the art would have no motivation to alter the Novo method by adding a coprecipitant to the biological compositions as claimed in claims 22 and 32.

Rejections under 35 U.S.C. §103 in view of Hawkins combined with Langley

Claims 1 – 5, 13 – 21, 23, 26 – 28, and 30 – 34 are rejected under 35 U.S.C. §103 in view of the Hawkins reference in combination with the Langley reference.

Both references generally teach a method of precipitating enzymes from aqueous solutions. However, the methods are fundamentally different, so one of ordinary skill in the art would not be motivated to combine the teachings of the references. Each of the methods begins with an aqueous solution or dispersion of polymer and enzyme. Hawkins combines the aqueous solution/dispersion with an organic solvent that is partly or fully miscible with the water of the aqueous solution to cause coprecipitation of the polymer and enzyme (col. 3, l. 28-30). Langley, on the other hand, combines the aqueous solution/dispersion (col. 4, l. 42-44) with an immiscible liquid and then azeotropes, i.e. distills, (Abstract) the combination to obtain a product of dry

particles in water immiscible liquid (col. 6, l. 61-65). One of ordinary skill in the art would not be motivated to substitute the Hawkins method of coprecipitation using a miscible organic solvent with the Langley method of distilling using an immiscible azeotropic liquid. Therefore, the references have not properly been combined.

The Office Action rejects Applicants' earlier assertion that there is no motivation to combine the references based on the argument that Langley is only used to demonstrate protein particles having a particular size. However, when combining references, each reference must be considered as a whole MPEP 2141.02. It has been demonstrated that one of skill in the art would not have thought to combine the teachings of the references because they teach different, incompatible methods of precipitating enzymes. The lack of motivation to combine the references can not be disregarded by selecting the particular particle size of Langley without viewing Langley in its entirety. Hawkins discloses nothing about the particle size of dehydrated particles, and there is no teaching in either reference that the resultant particles from Hawkins might happen to be the size of those particles disclosed in Langley.

The Hawkins and Langley references would not teach or suggest the claimed invention even if combined. Each of the claims recites, directly or indirectly, a coprecipitate core. Hawkins teaches maintaining the partially precipitated enzymes in a stable enzyme dispersion (col. 2, l. 14) with the option of drying the dispersion. There is no disclosure that the dried coprecipited product of Hawkins would form a particle having a coprecipitate core as that recited in the claims. Langley specifically states that the polymer coprecipitant forms a shell or matrix (Abstract) rather than a consolidated core as claimed. Thus, neither Hawkins nor Langley, alone or in combination, teach or suggest the coprecipitate core with dehydrated biological macromolecule coated thereon as recited in each of the claims.

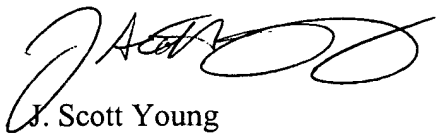
Conclusion

In view of the amendments and remarks made above, Applicant submits that the pending claims are now in condition for allowance. Applicant respectfully requests that the claims be

allowed to issue. If the Examiner wishes to discuss the application or the comments herein, the Examiner is urged to contact the undersigned by telephone.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,



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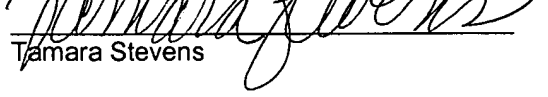

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